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Randomized cross-over evaluation of body-surface area-based dosing versus flat-fixed dosing of paclitaxel.

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PURPOSE: Despite dose calculation using body-surface area (BSA), pharmacokinetics of most anticancer drugs show wide interindividual variability. In this study, we evaluated the role of BSA in paclitaxel disposition. **PATIENTS AND METHODS:** Paclitaxel pharmacokinetics were prospectively studied in 12 patients that were treated in a randomized cross-over design with paclitaxel (3-hour infusion at a 3-week interval) at 175 mg/m² in cycle 1 (A) and a flat-fixed dose of 300 mg in cycle 2 (B), or vice versa. Blood samples were collected up to 24 hours after dosing and analyzed for total and unbound paclitaxel. **RESULTS:** The area under the curves (AUC) of unbound paclitaxel were similar in both dosing groups, with mean values +/- SD (A v B) of 1.34 +/- 0.158 versus 1.30 +/- 0.329 microM x h, indicating that BSA-based dosing reduced the coefficient of variation by 53.3%. Unbound and total paclitaxel clearance was also significantly related to various body-size measures, including BSA ($R > \text{or} = 0.617$; $P < \text{or} = .033$), weight ($R > \text{or} = 0.621$; $P < \text{or} = .031$), and lean-body mass ($r > \text{or} = 0.630$; $P < \text{or} = .028$). We hypothesize that this is caused by the association of paclitaxel in the circulation with Cremophor EL, the distribution of which is linked to total blood volume, and thus to BSA. **CONCLUSION:** This study indicates that paclitaxel disposition is significantly related to BSA. This provides a pharmacokinetic rationale for BSA-based dosing of this drug.

Publication Types:

- Clinical Trial
- Randomized Controlled Trial

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